REMARKS

The foregoing amendments to the specification and claims are respectfully submitted in response to the official action dated October 8, 2002. While there are a number of objections to the specification and claims in that official action, it is believed that the amendments to the specification, the addition of an abstract, and the cancellation of claims 1-28 and substitution of new claims 29-68 herein clearly obviates all of these objections. It is further submitted that these amendments do not include any new matter, and in addition applicants further submit that new claims 29-68 are fully patentable over the prior art. Therefore, reconsideration and allowance of these claims is respectfully solicited.

The Examiner has required a substitute specification in proper idiomatic English. Applicant have provided a substitute specification demonstrating not only that the present specification is fully in compliance with the applicable rules and statutes including 37 C.F.R. §§ 1.52(a) and (b), but that, once again, no new matter is included therein. In addition, an abstract has been submitted in compliance with 37 C.F.R. § 1.72(b).

Claims 4-28 have been objected to as being in improper form. However, the cancellation of these claims clearly obviates this objection. The claims have also been said to be generally narrative and indefinite, failing to conform with U.S. practice. However, once again, the cancellation of claims 1-28 also clearly obviates this rejection.

Claims 1 and 3 have been rejected as being unpatentable over Levin under 35 U.S.C. § 102(b). Levin is said to disclose a multi-compartment urinary bladder device with interconnecting valves and fluid flow controls, citing column 7, lines 16 *et seq.*, and Figures 11-13 thereof. This rejection is

respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Turning first to the Levin patent itself, this reference is basically directed to a pump device which is intended to act as a peristaltic prostheses and an energy-generating system for pacemakers and other devices. Thus, the principal figures in this patent relate to a pump which is disposed on opposite sides of a person's diaphragm, and which includes fluid-retaining sacs 12 and 14, which are adapted to receive a solution for transfer across the diaphragm. The Examiner, however, has specifically referred to the embodiment of Levin shown in Figures 11-13. This device is shaped to replace an injured urinary bladder, and includes internal multiple compartments which are interconnected by means of one-way valves 82. Thus, the conduits 40 and 42 of the pump in Levin are interconnected with these compartments.

It is clear that there is nothing whatsoever in Levin which teaches or even suggests an artificial urinary diversion apparatus as set forth in claim 29, and which includes, for example, a sphincter mechanism for opening and closing the outlet to the device, as well as control means for controlling the sphincter mechanism. It is only in this connection, however, that one is able to obtain such a device with near total control of the urinary continency being possible. In addition, applicants would also point to all of the further limitations set forth in dependent claims 30-68, none of which are suggested by Levin. It is therefore clear that all of these claims patentably distinguish over Levin, and withdrawal of this rejection is therefore respectfully requested.

Claim 2 has been rejected as being unpatentable over Leonard under 35 U.S.C. § 102(b). The Examiner contends that Leonard discloses a bladder prosthesis with multiple modular

parts, citing the claims and FIG. 1 thereof. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

The Leonard patent is broadly directed to implantable bladder prostheses. The device shown in Figures 1 and 2 of Leonard, for example, includes a liquid container 2 with at least two entrances, 3 and 4, and an exit 5, and which includes anti-reflux means 12 which includes chambers for free passage of liquid (*i.e.*, without valves) connected to liquid container 2 by constriction 16.

Once again, it is clear that Leonard in no way teaches or suggests the claims which are the subject of this application. The Leonard device does not disclose, *inter alia*, an artificial urinary diversion apparatus such as that which is claimed, particularly one which includes a sphincter mechanism for opening and closing the claimed outlet, as well as control means for controlling that sphincter mechanism. However, without the suggestion of such apparatus, it is clear that claim 29 is fully patentable over Leonard. Of course, the additional limitations set forth in dependent claims 30-68 are also nowhere taught or suggested by Leonard, so that each of these claims is also clearly patentable thereover.

As it is believed that all of the rejections set forth in the Official Action have now been fully met, favorable reconsideration and allowance of this application are earnestly solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that the Examiner telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which the Examiner might have.

Attached hereto are a substitute specification and abstract both in marked-up and clean copy versions.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: April 4, 2003

Respectfully submitted,

By _____

Arnold H. Krumholz
Registration No.: 25,428
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorneys for Applicant

422635_1.DOC

~~Description~~

ARTIFICIAL URINARY DIVERSION SYSTEM

FIELD OF THE INVENTION

[0001] The present invention relates to an artificial urinary diversion system ~~according to the generic term of claim 1~~.

BACKGROUND OF THE INVENTION

[0002] Among patients with urinary bladder disorder there ~~is~~ are a ~~plurality~~ number of ~~findings,~~ potential problems which require the removal of ~~the own~~ their bladders. In ~~this~~ these situations, a urinary diversion, by producing different sorts of reservoirs, is required. So-called wet diversions are ~~distinguished,~~ those with direct urinary diversion ~~via~~ through the ureters, which are implanted into the abdominal wall, or by insertion of a neutralized ~~part~~ portion of the intestine, in which the ureters are implanted, and which is for its part implanted into the abdominal wall.

[0003] In both cases the urine is collected in a urine bag, which is ~~stuck on the~~ attached to an orifice.

[0004] Alternatively, the ureters are implanted into the rectum or ~~more and more~~ increasingly in the past few years - into replacement bladders, which are made of neutralized parts of the intestine.

[0005] These replacement bladders are either connected ~~with~~ to the endogenous urethra, or they are conducted out of the body by creating an appropriate self-preserving occlusion mechanism at the abdominal skin, for example in the navel region.

[0006] Typical indicators for a replacement of the endogenous urinary bladder are advanced tumors ~~at~~ in the urinary bladder, but there are also malformations, bladder impairments due to inflammation, as well as functional

obstructions, such as ~~for example~~ obstructions by urinating, or development of bladder atrophies among paraplegics~~ people~~.

[0007] ~~Thus, it~~ It is ~~the~~ therefore one object of the present invention to create an artificial urinary diversion system, which is adaptable to the different ~~shapings~~ shapes of different persons, and which ~~shows~~ presents the largest possible filling volume.

[0008] ~~Further, it~~ It is ~~an~~ another object of the present invention~~,~~ ~~that the~~ to create artificial urinary diversion systems ~~can be created such~~ which are adaptable, without previous direct or indirect determination of the potentially available volume for said system such that ~~an~~ as effective as possible a determination and utilization during the surgical phase of the volume available in the patient is facilitated. ~~These objects are solved with the features of claim 1.~~

SUMMARY OF THE INVENTION

[0009] In accordance with the present invention, these and other objects have now been realized by the invention of artificial urinary diversion apparatus extending in a longitudinal direction comprising a first area having a plurality of first cross-sectional areas perpendicular to the longitudinal direction and a first outer surface, a second area having a plurality of second cross-sectional areas perpendicular to the longitudinal direction and a second outer surface, and a third area having a plurality of third cross-sectional areas perpendicular to the longitudinal direction and a third outer surface, the second area being disposed between the first area and the third area, the first area including at least one outlet, the third area including at least one inlet, at least one of the plurality of first and second cross-sectional areas being smaller than at least of one of the plurality of third cross-sectional areas and at least one of the plurality of first cross-sectional areas being greater than at least one of the plurality of second

cross-sectional areas, a sphincter mechanism for opening and closing the outlet, and control means for controlling the sphincter mechanism. Preferably, the first, second and third areas comprise a modular unit having the first, second and third outer surfaces adapted to provide a continuous outer surface for the apparatus.

[0010] In accordance with one embodiment of the artificial urinary diversion apparatus of the present invention, the apparatus includes fluid guide means for guiding a fluid directly from the third area to the first area through the second area.

[0011] In accordance with a preferred embodiment of the artificial urinary diversion apparatus of the present invention, the sphincter mechanism is disposed in the first area.

[0012] In accordance with another embodiment of the artificial urinary diversion apparatus of the present invention, the apparatus includes a sensor for sensing the filling level of the apparatus. Preferably, the apparatus includes alarm means for providing an alarm based on the filling level sensed by the sensor. Preferably, the alarm means comprises a sound or seismic alarm signal.

[0013] In accordance with another embodiment of the artificial urinary diversion apparatus of the present invention, the sensor is controlled by the nerves responsible for the control of the normal bladder.

[0014] In accordance with another embodiment of the artificial urinary diversion apparatus of the present invention, the outer surface of the apparatus comprising the first, second and third outer surfaces has a shape in a plane perpendicular to the longitudinal direction corresponding to the 6th polynomial function

$$F(x) = A + a_1x + a_2x^2 + a_3x^3 + a_4x^4 + a_5x^5 + a_6x^6$$

wherein A is between 0 and 2, a_1 is between 0 and 8, a_2 is between 0 and -2, a_3 is between 0 and 1, a_4 is between 0 and -0.1, a_5 is between 0 and 0.003, and a_6 is between -0.00001 and 0 and x is between 0 and 22.

[0015] In accordance with another embodiment of the artificial urinary diversion apparatus of the present invention, the outer surface of the apparatus comprising the first, second and third outer surfaces as a shape in a plane parallel to the longitudinal direction which corresponds to the 6th polynomial function

$$F(x) = A + a_1x + a_2x^2 + a_3x^3 + a_4x^4 + a_5x^5 + a_6x^6$$

wherein A is between 0 and 2, a_1 is between 0 and 8, a_2 is between 0 and -2, a_3 is between 0 and 1, a_4 is between 0 and -0.1, a_5 is between 0 and 0.003, and a_6 is between -0.00001 and 0 and x is between 0 and 22.

[0016] Preferably, the first, second and third outer areas are integrally formed.

[0017] ~~According to the application~~In accordance with the present invention, the second area, which is arranged between the first area and the third area, ~~shows~~ has a cross-sectional surface that is smaller than the cross-sectional surface of the third area. ~~By this it will be achieved, that~~ In this manner, a shape is provided~~,~~ which can be adapted to almost any patient, and more particularly, ~~it is achieved that~~ the largest possible filling volume can be provided~~, namely~~. This is accomplished by the simultaneous observance of the medical preconditions, such as ~~for example~~ that the arteries and the intestine that ~~pass~~ after the operation pass laterally to the second area, and on which no pressure must be ~~put on~~ applied. Attention must be paid to the fact that, ~~with~~ when a person ~~who~~ is standing erect, the third area is arranged above the second and the first area. For example, if ~~perhaps~~ the first area ~~shows~~ has a larger cross-sectional surface than the second area, ~~it is also achieved that~~ a so-called constriction

~~will be~~ is provided in the second area, which is necessary for the bypassing of arteries and/or the intestine and the kidneys, and ~~that~~ a positional fixing with the first area is ~~for example~~ possible at the pubic bone (Symphysis Pubica). ~~Further advantageous embodiments of the following invention are subject matter of the sub-claims.~~

[0018] ~~If, according to claim 2,~~ In accordance with another embodiment of the present invention, the first, ~~the~~ second and ~~the~~ third areas are modularly compounded, or rendered modularly compoundable, and ~~if it has been paid attention to the fact that~~ the respective transition surfaces between the individual areas are coordinated in a ~~way,~~ manner such that a continuous transition ~~is resulting,~~ results. In this manner, the advantage ~~will be~~ is achieved that, according to the respective spatial condition of the patient, the individual areas of the urinary diversion system can be compounded. ~~and thus, it~~ It will thus be possible to take ~~optimally~~ optimal account of the anatomical conditions of the patient.

[0019] ~~If, according to claim 4,~~ In accordance with another embodiment of the present invention, a fluid ~~guidance~~ guide is provided, which extends from the urinary bladder to the outlet in the first area~~, this~~. This corresponds, to a large extent, to the natural anatomy, ~~which means,~~ meaning that ~~among~~ with a person who is standing erect, the lowest, first area can be connected directly with the existing urethra, without using additional connection elements between the urethra and the outlet in the first area, which could possibly ~~cause~~ result in further medical complications.

[0020] ~~If, according to claim 5~~In accordance with another embodiment of the present invention, an actor, or ~~an~~ actuator, or a pump is provided in the third area, in which case there is no need to provide an external pump, and, in view of the ~~shaping~~ overall shape of the device, the first and ~~the~~ second areas are not negatively influenced. Furthermore, ~~with the~~

~~advantageous~~ in the embodiment ~~that~~ where an actuator or a pump ~~are~~ is provided in the third area, it is taken into account ~~to the fact~~ that ~~said~~ the third area, ~~which is optimally embodied~~ in an optimal embodiment, is most likely to have the most space for ~~the~~ integration of a pump without ~~extremely~~ significantly, or negatively, influencing the ~~shaping~~ overall shape.

[0021] ~~If, according to claim 6~~ In accordance with another embodiment of the present invention, the pump is formed as a telescope device~~, the~~. The advantage of this embodiment is that almost the ~~total~~ entire volume of the third area can be used for filling the ~~contained~~ urinary bladder ~~can be achieved~~ contained therein. Laboratory experiments have ~~already~~ shown that almost the ~~total~~ entire urinary bladder can be emptied with such a telescope device, without leaving any sediment in the urinary bladder.

[0022] ~~If, according to claim 7~~ In accordance with another embodiment of the present invention, the pump is formed as a lever pump~~,~~. In this case, the advantage is ~~achieved~~ that no complex mechanics ~~is~~ are integrated thereinto, such as ~~for example~~ for the use of a telescope device in the third area.

[0023] ~~If, according to claim 8~~ In accordance with another embodiment of the present invention, the pump is formed as a screw pump~~, also the~~. The advantage~~,~~ of this embodiment is that almost the total volume of the third area can be used for the urinary bladder~~, is achieved~~. In addition, by using a screw pump, ~~the advantage is given, that said~~ it is possible for screw pump ~~pulverizes~~ to pulverize possible smaller urine crystals, so that these pulverized crystals can also be passed through a stenotic urethra.

[0024] ~~If, according to claim 9, additionally~~ In accordance with another embodiment of the present invention, a screw pump is also arranged in a ~~way,~~ manner such that it ~~may~~ can possibly be displaced laterally to the fluid tube or duct~~,~~

~~the~~. In this embodiment, the advantage can be achieved~~,~~ that an inlet and a lavage of the artificial urinary diversion system can be ~~caused unproblematically~~ provided efficiently, as the fluid tube will be opened by moving the screw. This ~~practicability~~ possibility concerning the inlet and the lavage of the artificial urinary diversion system ~~is for example~~ can be very important in the field of spectroscopic examinations.

[0025] ~~If, according to claim 10~~In accordance with another embodiment of the present invention, a sphincter mechanism is preferably provided in the first area~~, the~~. In this embodiment, there is an advantage ~~is achieved,~~ in that almost ~~a~~ total control of the urinary continency is possible. ~~The control~~ Control of the sphincter mechanism can, for example, also be initiated externally.

[0026] ~~If, in addition, according to claim 11~~In accordance with another embodiment of the present invention, a control system is provided~~,~~ which regulates the sphincter mechanism~~,~~ ~~said~~. In this embodiment, the control system, which is ~~additionally able to assume~~ also capable of assuming further procedures, can ~~for example~~ also regulate the opening and ~~the~~ closing of the sphincter.

[0027] ~~If, according to claim 12~~In accordance with another embodiment of the present invention, a sensor system is provided that controls the filling level of the urinary bladder~~,~~. In this case, the person ~~concerned~~ involved will be ~~given~~ provided with a high degree of safety by using these artificial urinary bladders. This means that the person ~~concerned~~ involved does not have to void the urinary bladder regularly and in short intervals, but ~~said person~~ can integrate ~~in the~~ with everyday life in the usual ~~way~~ manner. If either a sound signal or a seismical signal is provided, which will ~~be produced at~~ result from a certain filling level of the bladder, ~~is sent to the concerned person, said~~ the person to whom it is provided can move normally in ~~the~~

everyday life. However, it should be ~~paid attention to the fact,~~ recognized that at least a security regulation is installed in the sensor system~~, which means,~~. In this manner, if a certain period of time elapses, for example 8 to 12 hours, ~~is exceeded, it~~ a signal should be ~~signaled~~ sent to the person to void the bladder, independent ~~from~~ of the filling level of ~~said~~ the bladder. Furthermore, when controlling the filling level of the artificial bladder ~~a~~ security can be ~~given~~ provided, which is oriented ~~at~~ towards the physiologically marginal conditions. ~~By this it will be achieved that~~ In this manner, the artificial urinary diversion system operates similar to the function of the natural urinary bladder. ~~This means, that~~ Thus, with ~~said~~ the urinary diversion system ~~it will be achieved that~~ of the present invention, similar to ~~the~~ natural processes, ~~first~~ the body first signals the person that the urinary bladder should be emptied, then the bladder will be opened, the urine will be pressed ~~out~~ or squeezed out, and the bladder will be closed again.

[0028] I~~f, according to claim 13~~In accordance with another embodiment of the present invention, the sensor system ~~will be~~ is controlled by the nerves responsible for the urinary bladder~~,~~. In that case, an almost natural feeling will be ~~given~~ provided to the concerned person with this neurological solution~~, which means,~~. Thus, an exogenous signal, such as for example that produced by a sound signal or a seismical signal, will ~~thus~~ not be necessary.

[0029] ~~If, according to claim 14~~In accordance with another embodiment of the present invention, a power supply is ~~additionally~~ also provided in the urinary diversion system~~,~~. In this manner, a compact urinary diversion device can be provided, which can for example first be integrated into the artificial urinary diversion system. However, ~~it is pointed out that~~ the power supply can also be arranged separately,

near the urinary diversion system in the patient, if, for reasons of space, a third area must be used, which does not allow an additional power supply.

[0030] ~~If, according to claim 15~~In accordance with another embodiment of the present invention, an external recharge device ~~will make~~ provides the power supply, ~~the advantage is achieved, that~~ in which case the urinary diversion system can be provided with almost lifelong ~~provided with~~ power. The charging of the counterpart of the external recharge device can be ~~made~~ provided by the adapted counterpart, which ~~is charging wireless~~ can be charged transcutaneously in a wireless manner, at an adapted main support ~~place~~ location, which is implanted subcutaneously.

[0031] ~~A simple~~ Simple power transfer can ~~for example~~ be achieved, for example, by ~~the fact, that~~ the recharge device ~~cooperates~~ cooperating inductively with the counterpart, with power being ~~for example~~ transferred inductively with frequencies tolerated by the body, for example 30 kHz.

[0032] ~~If, according to claim 17~~In accordance with another embodiment of the present invention, the power supply is ~~made~~ provided by primary batteries, which are integrated into the urinary diversion device~~, said~~. This embodiment of the urinary diversion device will work without any continuing maintenance, and the person concerned does not have to worry about the power supply.

[0033] It is also pointed out that, in case of a particular need, ~~for example~~ the power for the actor system and/or the sensor system can be transferred ~~wireless~~ transcutaneously in a wireless manner by placing a suitable transfer device onto the skin. However, it is ~~hereby~~ also necessary in that case that the controlling and providing can ~~also~~ be executed by primary batteries as an additional power source. It is also possible that the total control and sensor system can be interrogated and started by means of external telemetrically.

[0034] ~~If, according to claim 18, additionally~~In accordance with another embodiment of the present invention, an actor system is also integrated into the urinary diversion device~~, once again~~. In this case, a completely independent system is once again provided, which only needs to be connected at the inlets or outlets with functional structures of the patient's urinary diversion system, and which can be implanted as one compact ~~part~~unit.

[0035] ~~If, according to claim 19~~In accordance with another embodiment of the present invention, the third area is constructed bipartite or in two-part form with, dependent on the filling level of the urinary bladder, one part being able to move away from the other part~~,~~. In this case, it is ~~for example~~ therefore possible to flexibly adjust the size of the urinary bladder and the filling level, in accordance with the person's particular requirements.

[0036] ~~If, according to claim 20~~In accordance with another embodiment of the present invention, the urinary diversion device of the present invention ~~shows~~ includes two inlets in the third area, so that each ureter can be connected with the artificial urinary diversion systems.~~,~~ In this embodiment, it is thus not necessary to ~~possibly~~ provide a further separate additional element, for example in a Y-shape, which can be used~~,~~ if it is advantageous that the urinary diversion device ~~does only~~ have only one inlet.

[0037] By providing one or more anti-reflux valves in the third area, ~~in accordance with claim 21, it can be achieved that a~~ reflux of the urine into the kidney ~~is~~ can thus be stopped. This also prevents ~~a~~ possible ascent of bacteria from the bladder up to the kidney.

~~If, according to claim 22~~In accordance with another embodiment of the present invention, a fixing element is provided~~, it~~ which is easy to arrange and fix ~~it~~ in the human body.

[0038] If~~, according to claim 23,~~ the fixing element is connected with the urinary diversion device ~~via~~ by means of a dovetail joint, a tight or leak-proof connection ~~has been~~ can be constructed, and the fixing element can be kept in the body~~,~~ in order to later be ~~later~~ connected at the right place with the urinary diversion device.

[0039] ~~If, according to claim 24~~In accordance with another embodiment of the present invention, the fixing element is moveably fixed ~~via~~ by means of a guidance system~~,~~. In accordance with this embodiment, the urinary diversion device can, according to the anatomy of the person concerned, optimally be arranged and fixed. If ~~furthermore~~ the guide-rail system is also integrated into the third area, there are no rails available that are protruding the third area, which could possibly influence the arranging in the human body, or cause any functional or spatial inconvenience.

[0040] ~~If, according to claim 25~~In accordance with another embodiment of the present invention, the fixing element ~~shows~~ includes a splay or expanding element, which ~~for example widens~~ may widen after implanting into the guide rails~~,~~. In this case, a simple connection ~~possibility~~ is ~~given~~ provided, ~~with especially guarantying a particular~~ which can guarantee compatibility by the complete integration of the splay element into the fixing element.

[0041] ~~If, according to claim 26~~In accordance with another embodiment of the present invention, the fixing element is formed with a biocompatible material, such as silicone~~,~~. In this manner, a well-tolerated material is ~~given~~ provided, but also the elasticity of the silicone and ~~others~~ other materials are taken into account due to the splay movements of the splay element.

~~Further preferred embodiments of the present invention are subject matter of the remaining sub-claims.~~

BRIEF DESCRIPTION OF THE DRAWINGS

[0042] Referring to the following ~~drawings, said~~ detailed description, the artificial urinary diversion system will be described in detail ~~on the basis of a preferred embodiment.~~, and, in turn, refers to the drawings, in which:

[0043] Fig. 1 ~~illustrates a~~ is a side, perspective, schematic diagram of ~~said~~ the artificial urinary diversion system of the present invention;

[0044] Fig. 2 is a side, elevational, sectional ~~drawing among the intersection~~ view of the artificial urinary diversion system of Fig. 1, taken along line II - II thereof;

[0045] Fig. 3 ~~illustrates, in accordance with Fig. 1, a top view~~ is a top, elevational view of ~~said~~ the urinary diversion system of Fig. 1;

[0046] Fig. 4 ~~illustrates~~ is a bottom, elevational view of ~~said~~ the urinary diversion system of Fig. 1;

[0047] Fig. 5 is~~, in accordance with Fig. 1, said~~ an exploded, side, perspective view of the urinary diversion system ~~with separated single areas~~ of Fig. 1;

[0048] Fig. 6 is a side, elevational, sectional view of the ~~arranging of the~~ urinary diversion system of Fig. 1, arranged in a body during use thereof;

[0049] Fig. 7 is a front, elevational view of ~~said~~ the urinary diversion system as shown in Fig. 1;

[0050] Fig. 8 is a top, elevational view of ~~a body section regarding intersection~~ the urinary diversion system shown in Fig. 6, taken along line VII - VII thereof;

[0051] Fig. 9 ~~illustrates a diagram, which shows the~~ is a graphical representation of one executed polynomial function of 6^{th} degree regarding the top surface outline of ~~said~~ the urinary diversion system in accordance with Fig. 1;

[0052] Fig. 10 is a ~~diagram, which shows~~ graphical representation of the top-view silhouette of ~~said~~ the urinary

diversion system in accordance with Fig. 1, relating to the mentioned polynomial function of 6^{th} degree; and

[0053] Fig. 11 is a side, perspective of an embodiment of the fixing element used with the urinary diversion system of the present invention;

DETAILED DESCRIPTION

[0054] The ~~advantageous~~ particular embodiment of ~~said~~ the urinary diversion system ~~explained~~ of the present invention set forth in Fig. 1 includes a first area A, a second area B and a third area C, with the cross-sectional surfaces (illustrated hatched) that are perpendicular to the axial alignment of the urinary diversion device of the first, second and ~~the~~ third areas, being ~~so~~ constructed~~,~~ such that the cross-sectional surface Q1 of the first area A is larger than the cross-sectional surface Q2 of the second area B and the cross-sectional surface Q3 of the third area C is in each case larger than the cross-sectional surface of the first and ~~the~~ second areas. In addition, the first area A ~~shows~~ includes an outlet 3 and the third area C ~~shows~~ includes two inlets 5 for the urethras, which come from the respective kidneys.

[0055] The first area A of ~~said~~ the urinary diversion system shows at its bottom surface 7 an increasing area D, with the ~~shaping~~ shape possibly being linear, arched, concave or convex, dependent on the patient's anatomic conditions for the urinary diversion system. In Fig. 1 it ~~is~~ can be clearly ~~visible~~ seen that the second area B, which is arranged between the first area and the third area, is to be regarded as a constriction, with arteries being lead ~~by~~ laterally ~~to~~ past its surfaces 9. The third area C, which comprises a urinary bladder, is shaped ~~voluminously~~ so as to be voluminous enough to allow ~~a~~ for filling to as large a size as possible. The two inlets for the renal urethra are provided at the front side of the third area.

[0056] Fig. 2 illustrates a laterally sectional view ~~according to intersection~~ taken along line II - II. With this sectional view it is clearly ~~visible~~ seen that the urinary diversion device 1 presented in Fig. 2 shows the top-side of a first outline K1. Here, in contrast to Fig. 1, the elevation of the second area B to the bottom surface 7 of the first area A ~~is~~ can be more clearly ~~to see~~ seen. In this embodiment, a curved or curvilinear elevation is shown. ~~Said~~ The curved elevation serves ~~to be~~ for being brought into contact, for example, with the pubic bone, ~~and makes~~ thus ~~a~~ makes positional fixing possible. It ~~is~~ can also ~~visible~~ be seen in Fig. 2 that, below the third area, so-called guide rails 13 are provided, in which a fixing element (not shown) can be inserted. At this point, special attention shall be drawn to the fact that ~~a~~ protruding of the guide rails may, for example, be avoided by complete integration into the third area.

[0057] Fig. 3 illustrates a top view of ~~said~~ the urinary diversion system 1 and a second outline K2 in accordance with Fig. 1, with the constriction caused by the second area B being clearly visible, and with it being possible for the arteries ~~being possible~~ to be lead ~~by~~ laterally ~~of~~ past the side surfaces 9. The relative proportions~~, which are shown~~ between the first, ~~the~~ second and ~~the~~ third areas~~,~~ are also clearly visible.

[0058] Fig. 4 shows a bottom view of ~~said~~ the urinary diversion system 1. The ~~provided~~ guide rails 13 which are provided for the fixing element are clearly indicated.

[0059] Fig. 5 illustrates ~~said~~ the urinary diversion system 1, with its individual areas, i. e., the first, second and third areas, illustrated separately.

[0060] ~~At this point it shall be~~ It is also noted at this point that the division or sectioning into a first area, a second area and a third area describes a preferred embodiment.

~~Said~~ The urinary diversion system of the present invention can also be provided with only two areas or as an integral entity. On the other hand, ~~also~~ more than three areas can also be provided, which can be divided separately, ~~are imaginable,~~ with more areas of the increased adapting variation being taken into account.

[0061] Fig. 6 illustrates ~~for example the arranging~~ arrangement of ~~said~~ the urinary diversion system of the present invention in a human body. The first area A borders on the pubic bone, with the fixing element, which is moveably includable in the guide rails, being fixed, for example, at the respective places in the abdominal cavity.

[0062] Fig. 7 shows a front view for further illustration of the ~~arranging~~ arrangement of ~~said~~ the urinary diversion system shown in Fig. 6.

[0063] Fig. 8 is a top view, with the body section being above the section of ~~said~~ the urinary diversion system.

[0064] Fig. 9 ~~is for example~~ shows a fit curve of the polynomial form $f(x) = a_6x^6 + a_5x^5 + a_4x^4 + a_3x^3 + a_2x^2 + a_1x + a$, i. e. a polynomial of 6^{th} degree, which has been adapted to the first outline. The parameters used for this ~~adapting~~ adaptation are a_6 = ~~-9·10^6~~ $9x10^6$; a_5 = ~~-0,006~~0.006; a_4 = ~~-0,014~~-0.014; a_3 = ~~-0,1638~~0.1638; a_2 = ~~-0,9319~~-0.9319; a_1 = ~~2,6778~~2.6778 and a = ~~-0,8452~~0.8452. However, ~~it turned out that~~ within a domain of $0 \leq X \leq 22$ the coefficients a_1 to a_6 in the domains $0<A<2$; $0<a_1<8$; $-2<a_2<0$; $0<a_3<1$; $-0,1<a_4<0$; $0<a_5<0,003$ and $-0,00001<a_6<0$, within a domain of $0<x<22$, can be taken.

[0065] Fig. 10 illustrates a top view of the half of a second outline, which has also been approximated with a polynomial of 6^{th} degree. The parameters used for this ~~were~~ adaptation are a_6 = ~~-1·10^-5~~ $1x10^{-5}$; a_5 = ~~-0,008~~0.008; a_4 = ~~-0,0198~~-0.0198; a_3 = ~~-0,221~~0.221; a_2 = ~~-1,2703~~-1.2703; a_1 = ~~3,9521~~3.9521 and A = ~~-1,2557~~1.2557. ~~It has also turned out that~~

~~these~~ These coefficients can also be taken in the domains $0<A<2$; $0<a_1<8$; $-2<a_2<0$; $0<a_3<1$; $-0,1<a_4<0$; $0<a_5<0,003$; and $-0,00001<a_6<0$ within a domain of $0<x<22$, for adapting ~~the respective~~ this second outline. To illustrate that Fig. 10 is a top view, the first outline and the fitted curve have been reflected at y = 0 at the x-axis of the diagram.

[0066] Fig. 11 illustrates a fixing element 15 with a front area F, which can be introduced into the guide rails of ~~said~~ the urinary diversion system of the present invention, and an end area E, which can, for example, be pressed by hand.

[0067] Inside of ~~said~~ fixing element 15 there is a splay element (illustrated with dashed lines), which is, due to the upright side surfaces 19A to 19D, ~~for example~~ taken along with the elastically formed fixing element 15 in a manner so that, ~~for example,~~ when impacting on the end area, the arms of the splay element 17 in the front area ~~do~~ also move towards each other and take the elastic material of the fixing element 15 with them.

[0068] Thus, the fixing element 15 can be narrowed in such ~~a way,~~ manner that it can be included between the two guide rails 13. After introduction, the fixing element 15 ~~will~~ be released, so that, due to the elasticity of fixing element 15 the front area F will ~~be re-given~~ go back to its original shape, and a press fit/ tight fit may be achieved with the side surfaces of the guide rails. If ~~now~~ the fixing element 15 ~~shall be~~ is then moved within the guide rail 13, it is only necessary to re-press or re-contract the end area E, in order to open the press fit of the side surfaces of the front area F. The slots or openings 21 in the fixing element 13 serve ~~for being~~ to be tightly ~~lead~~ led by the guide rails when the position of the fixing element might be re-aligned.

[0069] Thus, with this fixing element 15 ~~said~~ the urinary diversion device of the present invention can be ~~arranged~~

suitably arranged before its final ~~arranging~~ disposition, and the fixing element can be fixed at the corresponding position in the abdominal cavity.

[0070] ~~Due to~~ In accordance with this additional ~~provision~~ embodiment, in which ~~is providing~~ a fixing element ~~that~~ is provided which is ~~separately to~~ separate from the urinary diversion system itself, it is also possible to pre-fix the fixing element at places which are difficult to access for fixing a fixing element, and to then introduce it ~~then~~ into the urinary diversion device.

[0071] Instead of the screw pump, ~~the~~ a pump using a telescope device, and ~~the~~ a lever pump, ~~all further sorts~~ various other types of pumps ~~are imaginable~~ can be used for squeezing out the urine, particularly a membrane pump or a gear pump.

[0072] The cross-sectional surfaces Q1, Q2 and Q3 can be different geometrical surfaces, such as quadratic, rectangular, trapezoidal, round, oval, elliptical or any other combination thereof.

[0073] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

~~Summary~~

~~Artificial Urinary Diversion System~~

ABSTRACT OF THE DISCLOSURE

~~The invention relates to an~~ An artificial urinary diversion system is disclosed, which consists of ~~at least one~~ a first area with at least one outlet, a second area, and a third area with at least one inlet for accommodating a urinary bladder. ~~The urinary diversion system is characterized in that the~~ The second area is arranged between the first area and the third area, and that the cross-sectional surfaces of the first and/or second areas which ~~is~~ are perpendicular to the axial alignment of the urinary diversion system ~~is~~ are smaller than the cross-sectional surface of the third area, thereby providing a shape that can be adapted to almost any patient. ~~The inventive~~ These artificial urinary diversion systems provide adaptable systems that can be produced without previous direct or indirect determination of the potentially available volume for ~~said~~ the system, and that facilitate an as effective as possible determination and utilization during the surgical phase of the volume available in the patient.

~~(Fig. 1)~~